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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/494,751	01/31/2000	Bernard Rees Smith	0769.00136	3862

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EXAMINER

DO, PENSEE T

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 03/01/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/494,751

Applicant(s)

SMITH ET AL.

Examiner

Pensee T. Do

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 October 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-90 is/are pending in the application.
- 4a) Of the above claim(s) 1-31 and 63-76 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 32-62, 77-90 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2. 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of group II, claims 32-62, in Paper No. 5 is acknowledged. The traversal is on the ground(s) that since there is a great amount of cross-classification amongst the sub-classes in this class, examination of all the claims in a single application would be efficient. More specifically, the kit is for use in a method as defined in the claims. Accordingly, they do relate to a single invention. This is not found persuasive because although the two groups are classified in the same class, they belong to different subclasses and the search for one subclass is not required for the other. Furthermore, the kit of group II can be used in a different method as mentioned in the previous office action. Thus, they are two distinctive inventions.

The requirement is still deemed proper and is therefore made FINAL.

Amendment Entry and Claims Status

The amendment filed on October 10, 2001 has been acknowledged and entered as paper number 5. Newly submitted claims 77-90 are examined along with the elected claims 32-62. Thus, claims 32-62, 77-90 are pending. Newly submitted claims 63-76 are non-elected.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 32-62, 78, 82-84, 88-90 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 32, line 8, "or when said TSH receptor is (ii) at least one binding agent which can bind to TRAb in such a way as not substantially to interfere with binding of said TRAb to said TSH receptor" is confusing. What does "(ii) refer to ? Furthermore, what is this phrase further limiting?

At least one "TSH" must be defined in the independent claim.

In claims 36-38, 40, please change "said agent" to –said binding agent—for proper antecedent basis.

Regarding claims 82, 83, 88-90, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claims 78 and 84 are indefinite for reciting "capable of" because it is unclear of how the fragment is modified to be capable of binding to the second epitope.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 32-36, 38-40, 48, 49, 77, 78, 79, 80, 82, 84, 85 are rejected under 35 U.S.C. 102(e) as being anticipated by Wondisford et al. (US 6,284,491).

Wondisford (US 6,284,491) teaches a synthetic TSH receptor which is labeled with radioactive iodine or other suitable labeling material such as chemiluminescent or fluorescent labels. These TSH receptors are used to produce antibodies which are then formulated in classic radioimmunoassay kits. These kits are supplied to the manufacturers to be used in a variety of standard assay methods (RIA, IRMA, Sandwich assays and the like).

Since the kit of the invention requires the receptor to be either:

- i) a porcine TSH receptor bound to a solid phase; or
- ii) a TSH receptor which is labeled; and

a binding agent which binds to (i) or (ii), Wondisford's teachings apply because the binder can be autoantibodies which bind to the receptor (ii). Patentable weight is not given to the functional usage of the binding agent in a kit claim. Therefore, the limitation "wherein the binding agent binds to the receptor in a competitive reaction with the analytes etc." is not given patentable weight in this instant case.

Regarding the means for incubating, means for reacting, means for detecting, Wondisford inherently discloses these means because materials to hold the components and means for detecting the labels must be present in order to carry out any assay method.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 32-34, 36, 37, 40, 41, 46-62, 77-90 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bergmann (US 5,814,361) further in view of Maclaren et al. (US 6,066,475).

Bergmann (US 5,814,461) teaches a method for the determination of an analyte, in particular of anti-TSH receptor autoantibodies, in a patient serum in which the reagents contain:

- A binder (B) for the analyte (A);
- A competitor (K) which binds by the binder (B) in such a way that the extend of its binding to the binder (B) is correlated with the presence of analyte (A) and /or its amount in the sample, the competitor is labeled and is added to the sample with the formation of a liquid reaction mixture;
- wherein the liquid reaction mixture is reacted simultaneously or subsequently with a solid phase for the selective immobilization of the

unbound competitor with respect to the binder and after quantitative separation of the solid phase from the liquid reaction mixture, the amount of the competitor bound to the solid phase is determined by means of the labels bound to the competitors.

The TSH receptor is a porcine TSH receptor (col. 7, lines 25-40).

Since Bergmann teaches that the liquid reaction mixture is reacted simultaneously with a solid phase, it is inherent that the TSH receptor is bound to the solid phase at some point in the assay.

Regarding the means for contacting the components with the sample, means for monitoring binding of the sample and the assay components to provide indication of the presence of analytes in the sample, these are inherently disclosed by Bergmann because any assay must require means such as at least a beaker to incubate the assay components and means to detect the label.

The limitation of claims 82, 83, 88 and 89 are not given patentable weight because these limitations are functional limitations. Functional limitations are not given patentable weight in a kit claim. Patentable weight is not given to the functional usage of the binding agent in a kit claim. Therefore, the limitation "wherein the binding agent binds to the receptor in a competitive reaction with the analytes etc." is not given patentable weight in this instant case.

However, Bergmann does not teach packing the assays components in a kit.

Maclaren teaches kits for assay of autoantibodies. (See col. 16, line 45-col. 17, line 8).

It would have been obvious to one of ordinary skills in the art to pack the assay reagents used in the method of Bergmann into a kit as suggested by Maclaren for economic convenience.

Claims 42-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wondisford in view of Tanaka (US 5,639,627).

Wondisford has been discussed earlier.

However, Wondisford does not teach the labeled antibody is indirectly labeled with an organic compound such as a biotin and the organic compound is coupled to a protein such as an avidin or streptavidin.

Tanaka teaches using organic compounds such as biotin/streptavidin as spacers for binding antigens to a solid support.(see col. 3, line 63-col. 4, line 15).

It would have been obvious to one of ordinary skills in the art to use biotin/streptavidin as a linkage compounds as taught in Tanaka in carrying out assays using the components of the kit taught by Wondisford because it would increase the sensitivity of the labels for the detection purpose.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is 703-308-4398. The examiner can normally be reached on Monday-Friday, 7:00-3:00.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 703-305-3399. The fax phone numbers for the

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organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-746-5291 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Pensee T. Do
Patent Examiner
February 11, 2002



CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP ~~1800~~ 1641